K011121
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NOV 16 2001

RÜSCH
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex Incorporated (USA)

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
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510(k) Summary

Submitter Name, Address:

Miss Karenann J. Brozowski
Group Regulatory Affairs Director
Rüsch International
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706
Facsimile: (603) 532-6207

Contact: Same as above

Name of the Device, Common, Proprietary (if Known), and Classification.

Classification Name: Urological Catheter & Accessories

Classification code: 78LJE

Common Name: Catheter, Nephrostomy

Proprietary Name: Rüsch Percutaneous Nephrostomy Catheter Sets

Identification of the legally marketed device to which the submitter claims equivalence.

The Rüsch Percutaneous Nephrostomy Catheter Sets is substantially equivalent to the Cook-Cope Loop Nephrostomy sets, and Boston Scientific Percutaneous Nephrostomy Set.

Description of the Device.

The Rüsch Percutaneous Nephrostomy Catheter Two Step Set consists of a Pigtail catheter with luer lock hub, Hollow blunt cannula with a luer lock hub and monofilament stylet, 2 part puncture cannula, Introducer Guide wire with a flexible "J" end and "J" straightener, an adapter to allow a connection of the catheter to a standard urine bag as well as a two-way stop cock.

The Percutaneous Nephrostomy Catheter Three Step Set consists of a Pigtail catheter with straightener and luer lock hubs, Introducer Guide wire with a flexible "J" end with "J" straightener, Sheath Dilator Assembly, a Three part puncture cannula with a luer lock hubs and Stainless Steel Stylet and Stainless Sheath, Funnel Adapter, and 2-Way Stop Cock.

Intended Use of the Device.

The Rüsch Percutaneous Nephrostomy Catheter Sets is intended for the percutaneous renal drainage via nephrostomy to relieve obstruction of urine flow.

Summary of Technological Characteristics.

The following technological characteristics are the same as or equivalent to predicate devices:

The Rüsch Percutaneous Nephrostomy Catheter Set, the Cook-Cope Loop Nephrostomy sets, and Boston Scientific Percutaneous Nephrostomy Set are equivalent in the following: Stainless steel guidewire coated with PTFE, Stainless steel puncture needle with hub, all contain a drainage catheter with connecting luer, all contain a dilator with hub and a stainless steel stylet with hub.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2001

Ms. Karenann J. Brozowski
Group Regulatory Affairs Director
Rüsch International
Tall Pines Park
50 Plantation Drive
JAFFREY NH 03452

Re: K011121
Trade/Device Name: Rüsch Percutaneous Nephrostomy Catheter Sets
Regulatory Class: Unclassified
Regulation Number: None
Product Code: 78 LJE
Dated: August 12, 2001
Received: August 21, 2001

Dear Ms. Brozowski:
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

NOV 1 6 2001

510(k) Number (if known): K011121

Device Name: Percutaneous Nephrostomy Catheter Sets

Indications for Use:

The Percutaneous Nephrostomy Catheter Sets is intended for the percutaneous renal drainage via nephrostomy to relieve obstruction of urine flow.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011121